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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,639	11/17/2003	Bruce W. Anderson	GP106-09.DV2	4320
21365	7590	03/22/2006	EXAMINER	
GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE SAN DIEGO, CA 92121			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 03/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,639

Applicant(s)

ANDERSON ET AL.

Examiner

LaToya C. Younger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-21 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 9 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/9/05 11/17/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7, 8, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, 8, 20 and 21 recite that the device and kit further comprise a wick. It is unclear as to where the wick is location in relation to the rest of the device/kit. Is the wick located in the cap or the container? Further clarification is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 4,515,752 to Miramanda.

Claim Interpretation – Claim 1 recites, “ means for positioning a specimen retrieval device along the inner surface of the vessel”. Applicants’ specification provides that the structural element suitable for carrying out this particular function is the combination of a conical wall of a frangible cap and the inner wall of the vessel holding a fluid substance. The Examiner further notes that while the means for

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positioning a specimen retrieval device along the inner surface of the vessel is recited in relation to a specimen retrieval device, the specimen retrieval device is not a positively recited limitation in claim 1.

Miramanda teaches a container (8) for holding a fluid substance (S). The container comprises an open top, a closed bottom and sidewalls. A cap (stopper 1) is used to close the open end of the container (8). The stopper contains multiple radial slits (3) making the stopper penetrable and allowing a fluid transfer device (pipette 9) to enter into the opening of the container (8) via the stopper (1). When the pipette (9) is inserted into the stopper (1), the radial slits (3) separate causing segments (4) to be forced downward toward the inner wall of the container (8). The downwardly positioned segments and the inner wall of container (8) form a means for positioning a specimen retrieval device along the inner surface of the vessel.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. Claims 2, 3, 10-19, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miramanda in view of US patent 4,803,998 to Kezes et al.

The disclosure of Miramanda is described above.

Miramanda fails to teach 1) a specimen retrieval device and 2), the radial slits of Miramanda are not the same as the claimed "striations".

Kezes et al teach a swab retaining vial and cap. Vial (12) is a vessel designed to container a fluid substance. Cap (14) is used to cover and seal the vial. Kezes et al teaches a specimen retrieval device (swab 10) for collecting a sample and placing the sample into the vial (12). Once the swab is placed inside the vial, the end of the swab handle that extends beyond the mouth of the vial (12) is easily removed by breaking along a score line (26). The swab can then be left in the vial and the cap placed on the vial for sealing.

It would have been obvious to one of ordinary skill in the art to provide a specimen retrieval device with the container and stopper of Miramanda to provide a means for collecting a culture sample or other similar sample. Kezes et al teach that it is common practice to use swabs to collect such samples. The swab taught by Kezes et al would be suitable for use with the device of Miramanda due to the presence of the score line which would make it easy to remove the excess handle portion of the swab and allow only the sample portion to remain in the vial, where it will be safe from outside contamination.

With respect to Miramanda's use of slits versus the claimed "striations", both are conventional means for allowing a pipette tip easy access to the opening of a container, while still somewhat maintaining the integrity of the cap and preventing contaminants from entering into the container. Score lines (striations) have been conventionally used as weakening lines in analytical device. It would have been obvious to one of ordinary skill in the substitute the slits of Miramanda for score lines since score lines would not immediately pierce the cap and jeopardize the contents of the container.

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Allowable Subject Matter

8. Claims 9 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya C. Younger whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Thursday 10:30 a.m. - 7:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lcy

M. J. Cole
MONIQUE T. COLE
PRIMARY EXAMINER